REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 22-38 are now pending in this application.

Claims 1-21 were canceled and new claims 22-38 were added to more particularly point out and distinctly claim the invention. The newly added claims are believed to be fully supported within the originally filed application also find support within a parent application serial no. 08/011,281 filed January 29, 1993 now issued as U.S. Patent 5,364,838 which patent was incorporated into the current application by reference and to which application the applicants have claimed priority under 35 U.S.C. §120.

Specific support for the newly added claims 22-38 can be found within issued patent 5,364,838 as follows:

New claim 22 is supported at col. 15, lines 54-67, col. 21, lines 6-9, col. 9, lines 23-25, col. 6, lines 39-42, col. 17, lines 16-27, col. 8, lines 29-57 and within the original claims.

New claim 23 is supported at col. 19, lines 30-36.

New claim 24 is supported at col. 20, lines 66-68, col. 21, lines 5-9, col. 7, lines 44-49, col. 6, lines 40-43, col. 17, lines 54-67, col. 9, lines 54-61 and col. 19, lines 30-36.

New claim 25 is supported in the same portions of the specification of the '838 patent above and in addition at col. 16, lines 60-61 with respect to the mouthpiece and also see col. 3, lines 41-45.

New claim 26 is supported at col. 7, lines 7-12, col. 9, lines 3-22 and col. 19, lines 30-36.

New claim 27 is supported at col. 20, lines 65-68, col. 9, lines 23-35, col. 21, lines 6-10, col. 7, lines 44-49, col. 3, lines 41-45 and col. 9, lines 54-61.

New claim 28 is supported at col. 7, lines 7-12, col. 9, lines 3-22, and col. 19, lines 30-36.

New claim 29 is supported at col. 13, lines 44-46, col. 15, lines 55-61, col. 20, lines 66-68, col. 9, lines 61-66, col. 15, lines 55-61, col. 21, lines 5-10, col. 17, lines 15-22, col. 3, lines 41-45 and col. 9, lines 54-61.

New claim 30 is supported at col. 7, lines 7-12 and col. 19, lines 30-36.

New claim 31 is supported at col. 15, lines 55-69 and col. 21, lines 5-10 and further at col. 15, lines 55-69, col. 21, lines 5-10, col. 8, lines 45-46, col. 17, lines 15-22, col. 9, lines 54-61 and col. 5, lines 41-54.

New claim 32 is supported at col. 21, lines 3-10, col. 9, lines 23-35, col. 6, lines 40-43, col. 15, lines 15-22, col. 16, line 59, col. 3, lines 41-45, and col. 9, lines 54-61.

New claim 33 is supported at col. 8, lines 25-46 and col. 5, lines 41-54.

New claim 34 is supported at col. 5, line 54 and col. 9, lines 58-61.

New claim 35 is supported at col. 15, lines55-69, col. 21, lines 5-10, col. 3, lines 41-45, col. 9, lines 54-61, and col. 17, lines 15-22.

New claim 36 is supported at col. 6, lines 33-45.

New claim 37 is supported at col. 17, lines 56-60.

New claim 38 is supported at col. 17, line 67 thought col. 18, line 6.

No new matter has been added

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

FORMAL MATTERS

The Examiner has indicated that the claims 32-52 have been renumbered. In that the claims were renumbered and claims 1- 21 have now been canceled, the new claims have been added as new claims 22-38.

The Examiner has objected to the drawings indicating that they should show "contacting the insulin with a compressed gas." Applicants traverse this objection and request its reconsideration and withdrawal. Applicants point out that the gas contacting the insulin will be invisible and that the insulin itself in a dry powder form will not be drawn in a manner which will add information to those skilled in the art looking at the disclosure. Those reading the application can readily understand that air can be forced against the dry powder insulin in order to create an aerosol cloud of aerosolized particles without the need for a drawing.

In that the Examiner has requested the proposed drawing applicants have attached such in the event that the objection is not withdrawn. Should the objection not be withdrawn applicants request that that the Examiner comment with respect to the appropriateness of the attached figure.

Double Patenting Rejection

The claims 1-21 were rejected over claims within the corresponding application. This objection has been rendered moot in view of the cancellation of claims 1-21 and the addition of new claims 22-38 which are not the same as the claims pending within the related application.

Rejection under 35 U.S.C. §102

Claims 1-3, 12, 13 and 17 were rejected under 35 U.S.C. §102(b) as anticipated by Laube et al. This rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicants have noted that the rejection was not applied against the claims which included the insulin as being in a dry powder form. All of the new claims 22-38 claim the insulin in a dry powder form. Accordingly, the rejection is not believed to be applicable with respect to the currently pending claims.

35 U.S.C. §103 Rejection

Claims 4-11, 16, and 18-21 were rejected under 35 U.S.C. §103 as unpatentable over Laube et al. in view of Newhouse et al. The rejection is traversed as applied against these claims and as it might be applied against the presently pending claims.

In making the rejection the Examiner recognized that Laube et al. did not disclose a dry powder form of insulin. To supplement the rejection the Newhouse et al. patent was cited. U.S. Patent 5,349,947 to Newhouse et al. is based on application serial no. 92,085 filed July 15, 1993. As pointed out above the present application claims priority to several earlier filed applications including application serial no. 08/011,281 filed January 29, 1993. Support for the above claims in applicant's U.S. Patent 5,364,838 having a filing date of January 29, 1993 has been pointed out above. Specific support with respect to dry powder insulin formulations is present in the '838 patent at col. 15, lines 54-67. In that applicant's disclosure is prior to that of Newhouse et al. the Newhouse et al. patent is not prior art to applicant's claimed invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Still further, it is applicants position that it would not be obvious to combine the references to obtain applicants invention. In deciding the question of obviousness under 35 U.S.C. §103 it is not realistic to pick and choose from any one reference only so much of it as will support a given position,

to the exclusion of other parts necessary to the full appreciation of what such a reference fairly suggests to one of ordinary skill in the art. Laube et al. does not suggest other forms of insulin for delivery beyond that which might be present within the metered dose inhaler canister 14. Newhouse et al. do not suggest using a metered dose inhaler canister. The mere existence in the prior art of the individual features of the claimed invention does not, without more, render the claims obvious within the meaning of 35 U.S.C. §103. The mere existence of dry powder insulin does not suggest that dry powder insulin should be used within devices and methodologies such as that taught by Laube et al. There must be positive evidence that the bringing together of such features or steps would have been obvious to an ordinarily skilled person. Here, it is only applicant's disclosure which teaches that dry powder insulin can be administered in accordance with the methodology claimed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Summarizing, the claim renumbering has been noted and the new claims have been added as new claims 22-38. The objection to the drawings is traversed and if the traversal is not accepted a proposed drawing is attached. The double patenting rejection is rendered moot in view of the cancellation of the claims 1-21. The 35 U.S.C. §102 rejection is rendered moot in that the claims rejected have been canceled and the new claims all include the term relating to dry powder insulin which claims were not rejected as anticipated over Laube et al. The 35 U.S.C. §103 rejection is also moot, but if applied here would be overcome by pointing out support in a parent application which is prior to the filing date of the Newhouse et al. reference. Accordingly, the rejections are believed to have been rendered moot or overcome and reconsideration and withdrawal are respectfully requested.

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-058CON3.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 23/DEC/02

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Attachments:

Proposed Figure 4
U.S. Patent 5,364,838
Mark-up copy of claims

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please cancel claims 1-21 without prejudice and add the following new claims 22-38.

23. (New) A method for treating diabetes mellitus in a patient comprising the steps of:

d. supplying a predetermined amount of dry insulin powder to an inhalation device;

e. releasing a pressurized gas over the predetermined amount of dry insulin powder to create an aerosolized suspension comprising powder suspended in air, wherein the aerosolized suspension contains an amount of insulin that is 2-10 times higher than the amount needed to be absorbed in the blood stream of the patient; and

f. inhaling the aerosolized suspension at a flow rate and volume sufficient to allow the patient to absorb in the bloodstream a controlled dose of insulin that comprises between 1- 50 units of insulin.

23. (New) The method of claim 22, wherein steps a-c may be repeated periodically as needed to treat the patient and wherein the amount of insulin supplied to the bloodstream in step c remains relatively constant for each repetition of steps a-c.

24. (New) A method of regulating blood glucose levels in a patient comprising the steps of:

a. supplying a predetermined amount of dry insulin powder to a chamber in an inhalation device;

b. contacting the predetermined amount of dry insulin powder with a propelling gas to create an aerosolized dry cloud suspension comprising insulin powder suspended in air;

c. inhaling in a single breath the aerosolized suspension at a breathing rate that is appropriate to allow bloodstream absorption of a controlled amount of insulin the controlled amount of insulin being adequate to create an acceptable serum glucose level in the patient; and

d. wherein steps a-c may be repeated periodically as needed to regulate the patient's blood glucose level and wherein the amount of insulin absorbed in step c remains is

relatively the same for each repetition of steps a-c.

25. (New) A repeatable method of regulating blood glucose levels in a human patient, the method comprising the steps of:

d. supplying a fixed quantity of dry insulin powder to a portion of a hand held inhalation delivery device;

e. propelling a gas over the fixed quantity of dry powder to produce, in a repeatable manner, an aerosolized suspension of insulin, the aerosolized suspension containing more insulin then is required in the blood stream of the patient to achieve a satisfactory blood glucose level; and

f. flowing at least a portion of the aerosolized suspension through a mouth piece on the device and into the lungs of the patient in a manner sufficient to cause the patient to absorb in the patients bloodstream a sufficient, controlled quantity of insulin to achieve acceptable blood glucose level following treatment.

26. (New) The method of claim 25, wherein steps a-c may be repeated periodically as needed to treat the patient and wherein the amount of insulin supplied to the blood stream in step c remains relatively constant for each repetition of steps a-c.

27. (New) A method of administering a sufficient amount of insulin to a patient to achieve blood glucose control via a hand held device that has a mouth piece, the method comprising the steps of:

e. mechanically delivering a predetermined amount of dry insulin powder to a part of the device, the predetermined amount of insulin being 2-10 times more insulin than is needed in the patient's bloodstream to lower serum glucose level to an acceptable value;

f. aerosolizing the dry powder to form a dry dust cloud in the device;

g. inhaling a single breath of the dry dust cloud,

h. causing the patient to absorb in the patient's blood stream a portion of the insulin inhaled in the single breath, the portion being a controlled amount that is sufficient to lower the patients blood glucose level to an acceptable level.

28. (New) The method of claim 27, wherein steps a-c may be repeated periodically as needed to treat the patient and wherein the amount of insulin supplied to the blood stream in step c remains relatively constant for each repetition of steps a-c.

29. (New) A method of treating diabetes mellitus in a patient comprising the steps of:

e. measuring the patient's blood glucose level;

f. supplying a predetermined amount of dry insulin powder to a hand held medical device; wherein the quantity of insulin powder supplied to the device is a function of the patient's blood glucose level;

g. aerosolizing the dry insulin powder with a compressed gas to create a dry cloud of insulin within the device; and

h. inhaling at least a portion of the dry insulin cloud at a flow rate sufficient to cause sufficient, controlled amount of insulin to be delivered to the patient's lungs for absorption into the patient's blood stream to produce an acceptable serum glucose level in the patient..

30. (New) The method of claim 28, wherein steps b-d may be repeated periodically as needed to treat the patient and wherein the amount of insulin supplied to the blood stream in step d remains relatively constant for each repetition of steps b-d.

31. (New) A repeatable method of lowering a patient's serum glucose level to acceptable value, the method comprising the steps of:

d. supplying a predetermined amount of dry insulin powder to a medical device;

e. releasing a compressed gas over the dry insulin powder to form a suspension comprised of dry insulin powder and air; and

f. inhaling at least a portion of the suspension at a flow rate and volume sufficient to deposit a sufficient, controlled quantity of insulin in the patient's lungs so that the patient absorbs into the blood between 1 and 50 units of insulin, thereby lowering the patient's blood glucose level to an acceptable value between 50 mg/dl and 300 mg/dl.

32. (New) A method of administering a controlled and repeatable dose of insulin that is effective to produce an acceptable serum glucose level in a diabetic patient whose blood glucose level is an unacceptable level, the method comprising the steps of:

d. creating a cloud of insulin powder within a hand held device, the cloud comprising insulin powder and a propelling gas, the cloud containing more insulin then is required to be absorbed by the patient to maintain an acceptable serum glucose level;
e. inhaling at least a portion of the cloud from the device;
f. facilitating the deposition of a sufficient and controlled quantity of insulin in the patient's lungs to cause the blood stream of the patient to absorb sufficient insulin to produce an acceptable serum glucose level.

33. (New) The method of claim 32, wherein the amount of insulin absorbed by the patient's bloodstream is between 1 and 50 units and the patient's blood glucose level is maintained at between 80 mg/dl and 200 mg/dl following the completion of step c.

34. (New) The method of claim 33, wherein the patient's blood glucose level is about 100 mg/dl after completion of step c.

35. (New) A method of administering insulin to a diabetic patient to control serum glucose levels via a hand held inhalation device, the method comprising the steps of:

d. supplying a predetermined quantity of insulin powder to a portion of the device;
e. aerosolizing the insulin powder to form a cloud of insulin within the device, the cloud comprised of air and suspended insulin particles, the insulin quantity of insulin particles being 2-10 times the dosage of insulin required to be delivered into the patient's blood to achieve acceptable blood glucose level;
f. administering to the patients blood stream via the patients lungs a sufficient controlled and repeatable quantity of insulin from the cloud to produce an acceptable blood glucose level in the patient.

36. (New) The method of claim 33, wherein the step of administering the insulin is accomplished by inhaling at least a portion of the cloud from the device at an inhalation rate and

volume that cause the insulin to be deposited into the patient's lungs in a manner that will cause absorption of a sufficient quantity of insulin to produce acceptable blood glucose level.

37. (New) The method of claim 34, wherein the rate and volume is predetermined and fixed.

38. (New) The method of claim 34, wherein the rate and volume are adjustable by the device.

Inventor(s): Igor Gonda
Title: METHOD OF TREATING DIABETES MELLITUS IN A PATIENT
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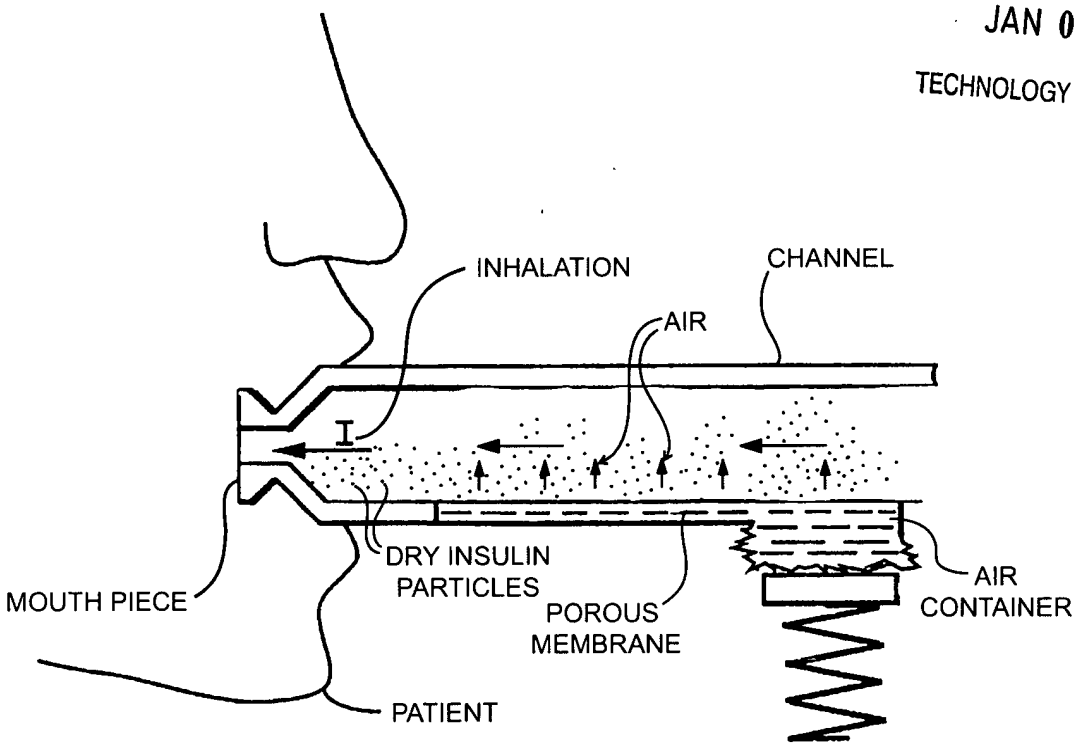

FIG. 4